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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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*Ex parte* EIJIRO WATANABE and KENJI OEDA

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Appeal 2008-3487
Application 09/301,766
Technology Center 1600

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Decided: August 7, 2008

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Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to nucleic acids encoding a raffinose synthase, vectors, cells and a method of production, which the Examiner has rejected as failing to comply with the written description requirement and failing to enable the full scope of the claims. We have jurisdiction under 35 U.S.C. § 6(b). We affirm in part.

*Background*

"It has been known that raffinose family oligosaccharides have an effect of giving good conditions of enterobacterial flora, if present at an appropriate amount in food" (Spec. 1). The Specification discloses that "[r]affinose family oligosaccharides are synthesized by the raffinose family oligosaccharide biosynthesis system beginning with sucrose in many plants." (Spec. 2). The Specification also notes that "[r]affinose synthase is the enzyme concerned in the reaction for producing raffinose by allowing a D-galactosyl group derived from galactinol to form the α (1→6) bond with the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule" (Spec. 2).

Appellants teach "isolating novel genes encoding raffinose synthase from various plants." (Spec. 3).

*Statement of the Case*

*The Claims*

Claims 1, 4, 5, 8-10, 16-23, 28, and 29 are on appeal. We will focus on claims 1, 4, 8, 10, and 16 which are representative and read as follows:

> 1. An isolated nucleic acid which comprises a polynucleotide encoding a protein that binds a D-galactosyl group through the α(1→6) bond to the hydroxyl group attached to the carbon atom at 6-position of the D-glucose residue in a sucrose molecule to form raffinose, wherein said polynucleotide comprises a nucleotide sequence selected from the group consisting of:
>
> (a) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3,

(b) a nucleotide sequence depicted by the 236$^{th}$ to 2584$^{th}$ nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 4,

(c) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 5,

(d) a nucleotide sequence depicted by the 134$^{th}$ to 2467$^{th}$ nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 6,

(e) a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7,

(f) a nucleotide sequence depicted by the 1$^{st}$ to 1719$^{th}$ nucleotides in the nucleotide sequence as depicted in SEQ ID NO: 8,

(g) a nucleotide sequence obtained from a polynucleotide which is amplified from a nucleic acid obtained from beet with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 11 and SEQ ID NO: 13 and a PCR primer selected from the group consisting of SEQ ID NO: 12 and SEQ ID NO:14, wherein said nucleotide sequence hybridizes with a nucleotide sequence complementary to the nucleotide sequence of (a) or (b), in a buffer comprising 0.9M NaCl and 0.09M citric acid at 65°C to 68°C, and

(h) a nucleotide sequence obtained from a polynucleotide which is amplified from a nucleic acid obtained from mustard or rapeseed with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 15, SEQ ID NO: 17 and SEQ ID NO: 19 and a PCR primer selected from the group consisting of SEQ ID NO: 16, SEQ ID NO: 18 and SEQ ID NO: 20, wherein said nucleotide sequence hybridizes with a nucleotide sequence complementary to the nucleotide sequence of any one of (c) to (f), in a buffer comprising 0.9M NaCl and 0.09M citric acid at 65°C to 68°C.

4. An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 3.

> 8. An isolated nucleic acid comprising a nucleotide sequence encoding the amino acid sequence as depicted in SEQ ID NO: 7.
>
> 10. An isolated nucleic acid comprising the nucleotide sequence as depicted in SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8.
>
> 16. An isolated nucleic acid comprising the nucleic acid of claim 1, which is operatively linked to a promoter.

The rejections as presented by the Examiner are as follows:

A. Claims 1, 4, 5, 8-10, 16-23, 28, and 29 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Ans. 3).

B. Claims 1, 4, 5, 8-10, 16-23, 28, and 29 stand rejected under 35 U.S.C. § 112, first paragraph as being nonenabled for the full scope of the claims (Ans. 5).

*A. 35 U.S.C. § 112, first paragraph Written Description rejection*

Appellants acknowledge that "SEQ ID NO: 7 (encoded by nucleotides 1 to 1719 of SEQ ID NO: 8) is indeed only a partial sequence of a raffinose synthase; about 25% of the full- length sequence is missing from the amino-terminal end" (App. Br. 13). Appellants argue that "the instant claim 1 does not recite that the claimed polynucleotide 'consists of' the recited sequence. Rather, the claim recites that the polynucleotide 'comprises' the recited polynucleotide, and hence also includes any amino acids necessary to complete an amino acid sequence of a raffinose synthase protein" (App. Br. 13). Appellants point out that "[t]wo such complete amino acid sequences

are disclosed in the present application as SEQ ID NOS: 3 and 5" (App. Br. 13).

Appellants further argue that the "Examiner's third argument is in the first place more related to the issue of enablement of the utility of the invention than to the written description of the structure of the invention" (App. Br. 14). Appellants contend that based upon successful experimentation "plainly the approach described in the specification can be used successfully to isolate a cDNA encoding RFS [raffinose synthase] from diverse genera of plants" (App. Br. 14). Appellants "submit that the evidence of record in the present application firmly establishes that it is 'more likely than not' that all of the sequences disclosed in the present application are those of RFS enzymes" (App. Br. 16).

The Examiner responds that the "description of a partial coding sequence, and hence a partial encoded amino acid sequence, does not adequately describe a protein having the claimed function" (Ans. 8-9). The Examiner also argues that the "application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined" (Ans. 10).

The Examiner also contends that a "description of a process by which a nucleic acid encoding a raffinose synthase enzyme may be isolated does not inherently describe the isolated nucleic acid" (Ans. 11).

In view of these conflicting positions, we frame the written description issues before us as follows:

(i) Does the Specification provide an adequate written description of nucleic acids which are defined as amplified from a source as in claim 1, (g) and (h)?

(ii) Does the Specification provide an adequate written description of nucleic acids comprising SEQ ID Nos where the complete sequence of the raffinose synthase protein is not disclosed?

*Findings of Fact (FF)*

1. The Specification provides the complete amino acid sequence of SEQ ID NO: 3 and the complete nucleic acid sequence SEQ ID NO: 4 (*see* Spec. 62-69).

2. The Specification teaches that "a nucleic acid containing raffinose synthase gene can be obtained by detecting a nucleic acid hybridizable to the gene fragment in DNAs of a gene library" (Spec. 19:16-18).

3. The Specification teaches that "[w]hen PCR is carried out by using the gene fragment as primers, it is possible to amplify a nucleic acid containing raffinose synthase gene from DNA derived from the desired organism" (Spec. 22:13-16).

4. The Specification teaches that the "raffinose synthase activity of the translated product of the gene of the present invention thus prepared can be measured by, for example, a method described in L. Lehle and W. Tanner" (Spec. 31:22-25).

5. The Specification teaches that the "full length raffinose synthase gene can be obtained by synthesizing new primers based on both

terminal sequences in the nucleotide sequence thus determined and carrying out PCR again" (Spec. 26:9-12).

6. The Specification teaches "a nucleic acid containing raffinose synthase gene can be detected by hybridization to DNA from the desired organism" (Spec. 21: 15-16).

*Discussion of the 35 U.S.C. § 112, first paragraph Written Description rejection*

*Claim 1*

We agree with the Examiner that the instant Specification does not describe the claimed genus of polynucleotides which are "amplified from a nucleic acid obtained from beet with a combination of a PCR primer selected from the group consisting of SEQ ID NO: 11 and SEQ ID NO: 13 and PCR primer selected from the group consisting of SEQ ID NO: 12 and SEQ ID NO: 13." Claim 1 also includes "mustard or rapeseed" in part h (Claim 1). The Specification discloses the amino acid sequence of SEQ ID NO:3 and one DNA sequence that encodes it (FF 1). That disclosure is adequate to describe all of the DNA sequences that encode the amino acid sequence of SEQ ID NO: 3. *See In re Wallach*, 378 F.3d 1330, 1333 (Fed. Cir. 2004) ("[T]he state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it.").

Claim 1, however, is not limited to polynucleotides comprising or encoding the amino acid sequence of SEQ ID NO:3-8. Appellants also claim polynucleotides "amplified from a nucleic acid obtained from a beet" (Claim 1). That is, the claimed polynucleotides are defined by three

characteristics: (1) they are naturally occurring in beet, mustard or rapeseed (Claim 1), (2) they are amplified using specific primers (FF 2-5), and (3) they hybridize to SEQ ID NO: 4 or nucleic acids encoding SEQ ID NO: 3 (for beet-derived polynucleotides) or one of: SEQ ID NO: 6, SEQ ID NO: 8, or nucleic acids encoding SEQ ID NOs: 5 or 7 (for mustard- or rapeseed-derived polynucleotides) (FF 6).

The critical question then, is this: is a disclosure of a method of obtaining members of a genus of nucleic acids sufficient to place those members in the possession of Appellants, even without any disclosure of which members of the genus have the "raffinose synthase" activity?

We conclude that describing a genus of chemical compounds is not necessarily adequate to support a claim limited to only those compounds that have a desired characteristic. Rather, the Specification must provide guidance regarding which compounds within the genus have the recited characteristic.

The court confronted facts similar to those here in *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004). In that case, the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human." *Id.* at 918. The patent "described in detail how to make cells that express either COX-1 or COX-2, but not both …, as well as 'assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product.['] " *Id.* at 927.

The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. *See id.* ("As pointed out by the district court, the '850 patent does not disclose just 'which "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.' … Without such disclosure, the claimed methods cannot be said to have been described.").

Just as in *University of Rochester*, the present application discloses a broad genus of chemical compounds (DNAs amplified from beet, mustard or rapeseed using raffinose synthase specific primers) but the claims are limited to only those compounds having a desired characteristic (encoding naturally occurring sequences with raffinose synthase activity). Just as in *University of Rochester*, the present Specification does not disclose which of the many possible DNAs which would hybridize to SEQ ID NOs 4, 6, or 8 or to nucleic acids encoding SEQ ID NOs: 3, 5, or 7 are naturally occurring sequences found in beets, mustard, or rapeseed and encode polypeptides having raffinose synthase activity.

The *University of Rochester* court specifically noted that the patent at issue there disclosed screening assays to identify compounds having the desired characteristic, but nonetheless held that the description was inadequate. The same holds true here.

Appellants argue that "Federal Circuit case law makes abundantly clear that it is permissible for an Applicant to claim an invention in product-

by-process terms. *See, e.g. Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002) and *Fiers v. Revel*, 25 USPQ2d 160, 1605 (Fed. Cir. 1993)." (App. Br. 14). We do not disagree with Appellants' statement that product-by-process claims may be statutory. However, we disagree that the instant product-by-process claims satisfy the written description requirement. As the *Fiers* court noted, "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993). The present Specification describes the method of obtaining the DNA, but does not provide a complete description of the DNA itself, as required by *Fiers*. *See id.* Similarly, the *Enzo* court noted that "[w]e stated that an adequate written description of genetic material 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention, and that none of those descriptions appeared in that patent" *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).

In our opinion, both the *Fiers* and *Enzo* decisions hold that possession of a nucleic acid requires more than simply a plan to isolate that nucleic acid and we, therefore, conclude that the Specification does not reasonably provide sufficient structure, formula, chemical name or physical properties to describe the claimed genus of nucleic acids recited in parts g and h of claim 1.

Appellants further contend that "showing reduction to practice of four species of the claimed invention obtained from three diverse genera of plants, adequately evidences that the inventors 'had possession' of the claimed invention at the time the present application was filed" (App. Br. 16).

We are not persuaded that a showing of four nucleic acids provides descriptive support for any raffinose synthase gene that can be amplified from any species of beet, mustard, or rapeseed. The Examiner has identified 13 species of beet and more than 50 species of mustard or rapeseed (*see* Ans. 12-15). The Nagasawa declaration supports the conclusion that the nucleic acid structure of raffinose synthase genes differ significantly between species members as Dr. Nagasawa shows that the species only share 60% or more homology (Nagasawa Dec. ¶ 2).

Here, the Specification provides no description of DNAs amplified from beet, mustard or rapeseed nucleic acids that would allow a person skilled in the art to determine whether a given DNA is within the scope of the instant claims using the sequences themselves.

We affirm the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, written description. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 16-23, 28, and 29 under 35 U.S.C. § 103(a) as these claims were not argued separately.

*Claim 4*

We agree with Appellants that claims 4 and 5 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Claims 4 and 5 are drawn to nucleic acids which comprise the complete raffinose synthase

gene. The Examiner argues that "the invention of claims 4 and 5 require a specific function, which the instant application does not sufficiently describe" (Ans. 17). In fact, the instant Specification sets out a specific assay for raffinose synthase (FF 4) and the Watanabe Declaration demonstrates measurement of raffinose synthase activity (*see* Watanabe Dec. ¶ 7).

> The Examiner
>
> "bears the initial burden . . . of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445(Fed. Cir. 1992). Insofar as the written description requirement is concerned, that burden is discharged by "presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."

*In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996).

The Examiner does not dispute that "SEQ ID NO: 3 is the amino acid sequence of the complete coding region of a cDNA obtained from a Chenopdiaceae plant (*Beta vulgaris*) in Examples 3 and 4" (App. Br. 17). The Specification positively states that SEQ ID NO: 3 is a raffinose synthase protein (Spec. 53:3-5). The Examiner has provided no evidence that SEQ ID NO: 3 does not encode a raffinose synthase.

We conclude that the Examiner has not set forth a prima facie case that claims 4 and 5 fail to comply with the written description requirement. We reverse the Examiner's rejection of claims 4 and 5.

*Claims 8 and 10*

We agree with the Examiner that claims 8 and 10 do not satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Claims

8 and 10 are drawn to nucleic acids which comprise the partial sequences of the raffinose synthase gene.

The Examiner contends that the "description of a partial coding sequence, and hence a partial encoded amino acid sequence, does not adequately describe a protein having the claimed function" (Ans. 8-9). Appellants respond that "the claim recites that the polynucleotide 'comprises' the recited polynucleotide, and hence also includes any amino acids necessary to complete an amino acid sequence of a raffinose synthase protein" (App. Br. 13). Appellants "submit that the missing 4% of that region (or for that matter the entirety of the missing amino-terminal portion) may be supplied by the corresponding amino-terminal end sequences of SEQ ID NO: 3 or 5 as desired by the practitioner of the invention" (App. Br. 18).

In *Wallach*, the court noted that "Appellants did not claim the nucleic acid molecules that encode the simple protein sequence that they disclosed. Rather, they claimed the nucleic acids encoding a protein for which they provided only a partial sequence." *In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004). The Wallach court further noted that "Appellants have not provided any evidence that the full amino acid sequence of a protein can be deduced from a partial sequence and the limited additional physical characteristics that they have identified." *Id.* at 1335. The court stated that "[u]ntil Appellants obtained the complete amino acid sequence of TBP-II, they had no more than a wish to know the identity of the DNA encoding it." *Id.* at 1335. Finally, the court concluded that "Appellants have provided no evidence that there is any known or disclosed correlation between the

combination of a partial structure of a protein, the protein's biological activity, and the protein's molecular weight, on the one hand, and the structure of the DNA encoding the protein on the other." *Id.* at 1335.

In our opinion, the instant facts track those of *Wallach*. Claims 8 and 10 are drawn to nucleic acids encoding proteins for which Appellants have acknowledged that they provided only a partial sequence (*see* App. Br. 18) and wish to know the identity of the DNA encoding that sequence (App. Br. 18). While Appellants have shown alignments between raffinose synthase genes (*see* Nagasawa Dec. Table 2), these very alignments show that the raffinose synthase genes differ significantly and that there is no reasonable expectation that the amino terminal ends of different raffinose synthase genes would sufficiently correlate to provide description of the structures of the undisclosed amino terminal DNA sequences of the nucleic acids of claims 8 and 10.

Appellants attempt to distinguish *Wallach*, by noting that "[i]n the instant case, raffinose synthases had been characterized in the prior art, and the instant specification provides the complete amino acid sequence of an enzyme demonstrated to have raffinose synthase (RFS) activity (SEQ ID NO: 5)" (Rep. Br. 2). However, in *Wallach*, a partial amino acid sequence of the specific allelic version of the TBP-II protein was disclosed and the issue was that the full length protein was not disclosed. *See Wallach*, 378 F.3d at 1335. Appellants' contention that disclosure of a sequence with "a high degree of sequence identity" should satisfy the description requirement (*see* Rep. Br. 2), when the actual missing amino terminal sequence of SEQ

ID NO: 7, for example, is not disclosed, is not consistent with *Wallach*. *See id*. at 1335.

We do not dispute Appellants' contention that SEQ ID NO: 7 is a raffinose synthase enzyme (App. Br. 18), but we are not persuaded by Appellants' argument that because "the skilled artisan can readily determine the exact structure or family of structures encompassed by the claims . . . there is no question that the inventors 'possessed' the inventions described in these two claims" (App. Br. 19). While the skilled artison could likely perform experimentation to obtain and determine the sequences encompassed by the claims, that is not the standard for "possession" under *Wallach*. "Until Appellants obtained the complete amino acid sequence of TBP-II, they had no more than a wish to know the identity of the DNA encoding it." *Id*. at 1335. The same situation applies here, where until Appellants obtain the complete sequence encompassed by the claims, they had a desire and likely the ability to possess the DNA, but did not have possession of the DNA itself.

We affirm the rejection of claims 8 and 10 under 35 U.S.C. § 112, first paragraph, written description. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claim 9 under 35 U.S.C. § 103(a) as this claim was not argued separately.

*B. 35 U.S.C. § 112, first paragraph Enablement rejection*

Claims 1, 4, 5, 8-10, 16-23, 28, and 29 stand rejected under 35 U.S.C. § 112, first paragraph, on the basis that the Specification

> while being enabling for an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, plants

> transformed therewith and methods of using such isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids encoding raffinose synthase.

(Ans. 5.)

The Examiner reasons that the Specification does not adequately enable the skilled artisan "to make and use the genus isolated nucleic acids from beet, mustard or rapeseed encoding a protein having raffinose synthase activity that are obtained by PCR using the recited primers and that would hybridize to a complement of such nucleotide sequences under the recited conditions" (Ans. 6).

Appellants argue that

> First, the skilled artisan can follow detailed teachings in the specification of how to clone, express and evaluate DNAs that are likely to encode functional raffinose synthase enzymes. It is true that it is a bit unpredictable whether any individual clone made in an experiment will include a DNA encoding a functional enzyme, but it is not unpredictable whether the skilled artisan would succeed in identifying at least one functional DNA in an experiment as a whole. To the contrary, it is very likely that the skilled artisan would find a cloned DNA encoding a functional enzyme by following the teachings of the specification.

(App. Br. 25.)

In view of these conflicting positions, we frame the enablement issue before us as follows:

Would it have required undue experimentation to identify alternative raffinose synthase gene sequences from beet, mustard, or rapeseed?

*Findings of Fact (FF)*

*Breadth of the Claims*

7. Claim 1 is not limited to the specific sequences disclosed in the Specification but is open to sequences with alternate amino terminal regions and which are capable of being amplified by specific DNA primers (*see* Claim 1).

*Presence of Working Examples*

8. The Specification discloses four different nucleic acid sequences for partial or complete raffinose synthase genes (*see* Spec. 8).

*Amount of Direction or Guidance Presented*

9. The Specification teaches a specific assay to identify nucleic acids which encode proteins with raffinose synthase activity (Spec. 31:22-33:9).

10. The Specification teaches 4 different nucleic acid sequences of raffinose synthase type genes (Spec. 8).

11. The Specification teaches techniques to obtain raffinose synthase genes from other species including PCR amplification (Spec. 24-26).

12. The Specification teaches RFLP analysis (Spec 27:13-18).

*State of the Prior Art and Unpredictability of the Art*

13. The Examiner cites Duggleby[1] to show that "the function of any DNA sequence, whose identity is based solely on homology, can only

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[1] Ronald Duggleby, *Identification of an acetolactate synthase small subunit gene in two eukaryotes*, 190 Gene 245-249 (1996).

be proven by experiments designed to evaluate that function" (Ans. 6).

*Quantity of Experimentation necessary*

14. The Examiner made no factual findings regarding the quantity of experimentation necessary to carry out the invention.

*Discussion of 35 U.S.C. § 112, first paragraph Enablement rejection*

"The essential question here is whether the scope of enablement … is as broad as the scope of the claim[s]." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991).

We agree with the Appellants that the Examiner has not provided sufficient evidence to show that it would have required undue experimentation to practice of the full scope of the claimed invention.

Other than breadth of the claims, the other *Wands* factors favor Appellants, particularly "the amount of direction or guidance presented", "the state of the prior art",and "the relative skill of those in the art," *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988).

We specifically find that the factor of "the predictability or unpredictability of the art" weighs in favor of Appellants, since the use of PCR to clone a gene of interest from related species is routine as shown by Peterbauer[2], who teaches that "[t]o isolate a cDNA encoding for raffinose synthase by reverse transcription-PCR, degenerate oligonucleotide primers were designed based on amino acid motifs conserved among *Cucumis*

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[2] Thomas Peterbauer et al., *Functional expression of a cDNA encoding pea (Pisum sativum L.) raffinose synthase, partial purification of the enzyme from maturing seeds, and steady-state kinetic analysis of raffinose synthase*, 215 Planta 839-846 (2002).

*sativus* raffinose synthase, stachyose synthases and related sequences" (Peterbauer 841, col. 2).

> It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. *In re Angstadt*, 537 F.2d 498, 502-03 [] (CCPA 1976). However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.

*In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991). In the instant fact pattern, there is significant disclosure of methods for making and screening raffinose synthase genes (*see* FF 8-13).

We are not persuaded by the Examiner's argument that the "claim does not recite any specific PCR conditions by which the 'product-by-process' is produced" (Ans. 21). The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention and no such evidence or scientific reasoning is present in the instant rejection. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993) (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). In particular, we agree with Appellants that, based on Peterbauer's teachings (*see* Peterbauer 840), PCR cloning of related genes like raffinose synthases has a success rate much greater than that found sufficient in *Wands* (*see* App. Br. 25).

We also do not find persuasive the Examiner's argument that the "instant specification does not teach any structural feature that would be recognized by one of skill in the art at the time of the invention, identifying a raffinose synthase and distinguish a raffinose synthase for other encoded proteins" (Ans. 24). We note that claim 1 recites a specific activity for raffinose synthase and the Specification teaches an assay for this activity (FF 3). The Examiner has provided no reason or evidence to support the position that the ordinary artisan could not identify whether a protein had raffinose synthase activity and therefore has failed to establish a reasonable basis to question the enablement.

We reverse the rejection of claims 1, 4, 5, 8-10, 16-23, and 28-29 under 35 U.S.C. § 112, first paragraph, enablement.

CONCLUSION

In summary, we affirm the rejection of claim 1, 8, and 10 under 35 U.S.C. § 112, first paragraph, written description. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 9, 16-23, 28, and 29 under 35 U.S.C. § 103(a) as these claims were not argued separately.

We reverse the Examiner's rejection of claims 4 and 5 under 35 U.S.C. § 112, first paragraph, written description.

We reverse the rejection of claims 1, 4, 5, 8-10, 16-23, and 28-29 under 35 U.S.C. § 112, first paragraph, enablement.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

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